

## ICH Q3D(R1) EWG Work Plan

### 9 February 2017

**Topic Adopted:** October 2009

(Maintenance for Cutaneous and Transdermal Routes approved September 2016)

**Last Face-to-Face Meeting:** Strasbourg, France – June 2015

### 1. Anticipated Milestones

Completion Date	Deliverable
May 2018	Finalize <i>Step 2</i> cutaneous and transdermal PDEs document and publish for public comment
May 2019	Finalize <i>Step 4</i> document

### 2. Timelines

Date	Task / Activity	Details
1 March 2017	Confirm interest and resources to move forward with cutaneous and transdermal PDEs	➤ EWG members will be contacted to confirm interest and time commitment.
1 April 2017	Initiate development of permitted daily exposures for the cutaneous and transdermal routes of administration. Define whether cutaneous and transdermal PDEs are necessary for all or some of the 24 elements in the ICH Q3D Guideline.	➤ Schedule teleconferences ➤ Develop work plan and delegate work
November 2017	EWG meets for F2F meeting	➤ Review progress on cutaneous and transdermal PDE development
May 2018	Finalize <i>Step 2</i> PDEs for cutaneous and transdermal route of administration. Publish for public comment.	➤ It is anticipated that this work will require 12-18 months to complete. PDEs to be distributed for public comment.

June 2018 – November 2018	<i>Step 3</i>	➤ Internal/external consultation in ICH regions
November 2018 - April 2019	EWG telecon/e-mail consultation	➤ Reviewing and resolving comments received from consultation process; preparing <i>Step 3/4</i> document
May 2019	<i>Step 3</i> signoff	➤ Postal signoff <i>Step 3</i> by the Regulatory Experts.
May 2019	<i>Step 4</i>	➤ Adoption by the Regulatory Members of the Assembly.